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M.J.

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/485,129 06/07/95 WALLACH

D WALLACH=5B

001444 HM12/0130
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EXAMINER

SCHWADRON, R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED:

01/30/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 08/485,129	Applicant(s) Wallach et al.
Examiner Ron Schwadron, Ph.D.	Group Art Unit 1644



Responsive to communication(s) filed on _____.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 11-14, 35-39, and 43-64 is/are pending in the application.

Of the above, claim(s) 14, 39, 45, 50, 55, 62 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 11-13, 35-38, 43, 44, 46-49, 51-54, 56-61, 63, 64 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Newly submitted claims 55 and 62 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The previous elected invention is drawn to DNA, expression vectors containing said DNA, and host cells containing said expression vectors, classified in Class 435, subclasses 320.1, 240.2 and 252.3, and Class 536, subclass 23.5. The invention of claims 55 and 62 are drawn to a process for producing a protein, classified in Class 435, subclass 69.1. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as preparation of DNA probes that can be used in hybridization assays to detect TBP-II DNA in cells. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II and Groups I and II have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 55 and 62 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Claims 11-13,35-38,43,44,46-49,51-54,56-61,63,64 are under consideration.

RESPONSE TO APPLICANTS ARGUMENTS

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 11-13,35-38,43,44,46-49,51-54,56-61,63,64 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

The specification does not provide adequate written description of the claimed invention for the reasons elaborated in the previous Office Actions. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the ..claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed DNAs and molecules containing said DNAs.

Regarding applicants comments in the instant Brief, applicants comments are based on the syllogism enunciated in page 13 of said Brief. In said syllogism, applicant appears to argue that the DNA sequence encoding TBP II is an inherent property of the TBP II protein visa vie the inherent amino acid sequence of TBP II. However, the DNA sequence is not an inherent property of the TBP II protein because proteins do not encode nucleic acids. Regarding point 2 of said syllogism, while the amino acid sequence of TBP II is an inherent property of said protein, the nucleic acid sequence encoding said molecule is not an inherent property of the protein. There is no disclosure in the specification of the nucleic acid sequence of a DNA molecule encoding TBP II. The amino acid sequence of TBP II is not disclosed in the specification. While the amino acid sequence of TBP II is an inherent property, in order to determine the nucleic acid sequence based on said

sequence, disclosure of said sequence is required as is the conversion of the amino acid sequence into appropriate nucleic acids encoding said protein. The amino acid sequence of TBP II was not known by applicant at the time of filing of the instant application, therefore, applicant was not in possession of the claimed nucleic acids. Furthermore, there is no disclosure in the specification of the nucleic acid sequence of a DNA encoding TBP II. It is also clear that a DNA sequence encoding a protein is not an inherent property of a protein. Applicants syllogism puts forth an argument as to why the DNA sequence encoding TBP II would be obvious based on the inherent amino acid of TBP II. In view of the fact that there is no literal description of a nucleic acid sequence encoding a DNA sequence in the specification, applicants syllogism would at best explain why the claimed nucleic acid is obvious in view of the inherent amino acid sequence of the TBP II protein. However, obviousness is not the appropriate standard with regards to issues of written description. The CAFC stated in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1997) that:

3. Patentability/Validity -- Specification -- Written description (§ 115.1103)

Patent's entitlement to earlier filing date extends only to that which is disclosed in prior application, and does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed; one shows that one is "in possession" of invention of patent by describing invention, with all its claimed limitations, not that which makes it obvious, and although prior application need not describe claimed subject matter in exactly same terms used in claims, prior specification must contain equivalent description of claimed subject matter, and description which renders obvious invention for which earlier filing date is sought is not sufficient.

The CAFC also stated in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977) that:

The invention is, for purposes of the 'written description' inquiry, whatever is now claimed .") (emphasis in original). One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. Although the exact terms need not be used in haec verba , see Eiselstein v. Frank , 52 F.3d 1035, 1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995) (" [T]he prior application need not describe the claimed subject matter in exactly the same terms as used in the claims... ."), the specification

must contain an equivalent description of the claimed subject matter. A description which renders obvious the invention for which an earlier filing date is sought is not sufficient.

There is no disclosure in the specification of an isolated nucleic acid encoding TBP II or the nucleic acid sequence encoding said molecule. Therefore, at the timing of filing applicant was not in possession of the claimed invention. While applicants syllogism establishes why the claimed nucleic acid would be obvious based on the inherent amino acid sequence of TBP II, obviousness is not the appropriate standard for written description. Regarding claims 35-38,43,44,46-49,51-54,56-61,63,64 there is no disclosure in the specification of nucleic acids encoding the fragments of TBP II recited in the claims. Applicants syllogism does not disclose the identity of said fragments or even render the identity of said fragments obvious.

5. Claims 35-38,43,44,46-49,51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the claimed DNA molecules encoding the fragment of claim 35, part (2) or claim 36, part (2) or claim 46, part (2) or claim 51, part (2). Regarding original claim 11, said claim is drawn to a DNA molecule encoding TBP II, not a fragment thereof. There is no disclosure in the specification as originally filed of DNA molecules encoding the aforementioned fragments recited in the claims. There is no written description of the scope of the claimed inventions in the specification as originally filed (the claimed inventions constitute new matter).

Regarding applicants comments, the specification page 15, lines 11-17 refers to protein molecules, not nucleic acid molecules. Regarding the specification, page 4, said passage refers to nucleic acids encoding proteins, not fragments of a protein with a particular functional activity. Regarding the specification, page 7, said passage of the specification refers to proteins and also does not specify that "proteins substantially homologous" refers to protein fragments with a particular functional activity. Regarding the specification, page 9, lines 13-21, said passage refers to oligonucleotides used as probes to detect the DNA encoding TBP-II. This is not the claimed invention. The specification page 16 also does not disclose the scope of the claimed invention (eg. a nucleic acid

encoding a fragment with the functional activity recited in the claims. Applicant appears to be arguing that the instant limitation is obvious in view of the disclosure of the specification. However, obviousness is not the appropriate standard with regards to issues of written description. The CAFC stated in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1997) that:

3. Patentability/Validity -- Specification -- Written description (§ 115.1103)

Patent's entitlement to earlier filing date extends only to that which is disclosed in prior application, and does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed; one shows that one is "in possession" of invention of patent by describing invention, with all its claimed limitations, not that which makes it obvious, and although prior application need not describe claimed subject matter in exactly same terms used in claims, prior specification must contain equivalent description of claimed subject matter, and description which renders obvious invention for which earlier filing date is sought is not sufficient.

The CAFC also stated in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977) that:

The invention is, for purposes of the 'written description' inquiry, whatever is now claimed .") (emphasis in original). One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. Although the exact terms need not be used in haec verba , see Eiselstein v. Frank , 52 F.3d 1035, 1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995) (" [T]he prior application need not describe the claimed subject matter in exactly the same terms as used in the claims. . . ."), the specification must contain an equivalent description of the claimed subject matter. A description which renders obvious the invention for which an earlier filing date is sought is not sufficient.

6. Claim 63 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the claimed DNA molecules. The oligonucleotides disclosed in pages 9-11 of the specification are

complementary to the DNA encoding TBP-II. Therefore, they do not encode TBP-II, because they are antisense to the TBP-II molecule. The instant claim recites oligonucleotides that encode DNA encoding TBP-II. There is no disclosure of such an invention in the specification as originally filed.

7. No claim is allowed.
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.
10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone

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number is (703) 308-0196.

Ron Schwadron
Primary Examiner
Group 1800-1644

Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644

January 29, 2001